



Attorney Docket No. 016777-0463

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant: Daniel J. DRUCKER et al.
Title: GLP-2 RECEPTOR GENE PROMOTER
AND USES THEREOF
Appl. No.: 09/833,740
Filing Date: April 13, 2001
Examiner: Scott David Priebe
Art Unit: 1632

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REPLY BRIEF

Sir:

This Reply Brief is filed within two months of the Examiner's Answer dated May 19, 2004 and is filed in triplicate under the provisions of 37 C.F.R. § 1.192. Nevertheless, the Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Appellants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

In the Examiner's Answer, Mr. Priebe maintains that the subject application fails to satisfy 35 U.S.C. § 112 because it lacks sufficient written description to show possession of the claimed invention at the time of filing, and also that the claims do not distinctly claim the subject matter of the invention. By refusing to consider the specification *in toto*, however, the Examiner errs as a matter of law in his "written description rejection." Additionally, the Examiner errs factually because he incorrectly interprets both the specification and the claims.

Errors as a Matter of Law

The Examiner incorrectly evaluates the descriptive factors individually, rather than considering the specification as a whole. This is improper because the court in *Enzo* taught that multiple factors, alone or *in combination*, can show “possession” of the invention, in a conceptual sense, in satisfaction of the written description requirement. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 964, 964 (Fed. Cir. 2002).

As Appellants explained in their Appeal Brief, the *Enzo* factors, which are essentially those set forth in the U.S. Patent Office Written Description Guidelines, provide a map for a skilled person to identify and utilize the GLP-2R promoter region. Guidelines, 66 Fed. Reg. 1099 at 1106. For example, the specification as a whole teaches the location of the GLP-2R promoter region on the GLP-2R gene, a partial sequence of both the mouse and human promoter regions, the amount of the promoter region that is necessary and sufficient to create a construct containing the GLP-2R promoter region, and the desired function of the promoter region. Specification, paragraph 43.

All of these factors together allow a skilled person to locate the GLP-2R promoter region, to utilize the necessary portion of the GLP-2R promoter region, and to identify the GLP-2R promoter region through the GLP-2R promoter construct's function. Therefore, the specification considered in its entirety describes the GLP-2R promoter region in sufficient detail to show Appellants' possession of the invention.

Errors as a Matter of Fact

As elaborated below, several new mistakes of fact appear in the Examiner's Answer, relating to one or the other of the appealed rejections.

The Examiner alleges that the specification does not show possession of the “promoter region of a GLP-2R gene” because it does not sufficiently distinguish the GLP-2R promoter region from other promoters or DNA sequences. Examiner's Answer, page 7. This allegation is not true. The specification in paragraph 0103 compares the sequences of the 5'-untranslated region and 5'-flanking region of the three receptors in the G protein couple receptor superfamily. This comparison did not show a significant similarity over 5'-untranslated or putative promoter regions of the three related G protein

receptors. In contrast, the first 200 nucleotides of the human and mouse GLP-2R promoter regions did exhibit sequence similarity. Specification, paragraph 0104.

While the specification teaches that the GLP-2R promoter region exhibits some homology between the mouse, human, and rat species, it is evident that no such structural similarity exists between the three promoter regions within the G protein promoter superfamily. Thus, the specification teaches that the GLP-2R promoter region is distinguishable from other promoter regions, and even from related promoter regions, and therefore, describes the GLP-2R promoter region in a manner sufficient to show possession of the invention and satisfy the written description requirement.

Additionally, the Examiner newly alleges that Appellants do not describe the sequences that are necessary for the construct to retain GLP-2R promoter function. Examiner's Answer, page 7. Again, the Examiner is mistaken. The specification sets forth a minimum number of nucleotides, "at least the last 1,000," that are required for the "promoter region of the GLP-2R gene." Specification, paragraph 43. As the Examiner himself indicates, on page 7 of his Answer, "several potential transcription factor recognition sequences are identified ... within the first 180 nucleotides of the transcription start site." Thus, the Examiner admits that the mentioned recognition sequences are within the promoter region as described, regardless of whether they are individually identified.

With regard to the indefiniteness rejection, the Examiner likewise mistakenly argues a lack of clarity with respect to the number of nucleotides, upstream of the transcription start site, to constitute a "promoter region of the GLP-2R gene," as recited. Referring to the specification at paragraph 0043, the Examiner states that the minimum number of nucleotides is "at least 1000 bases, at least 1200, bases, and at least 1400 bases." Examiner's Answer, pages 14 and 15. Yet, the specification actually reads "at least about 1000 bases," "suitably at least about 1200 bases," and "desirably at least about 1400 bases." Thus, the specification is clear and definite that "at least about 1000" bases is the minimum number of nucleotides needed for the promoter region of the GLP-2R gene, at least 1200 bases would be better, and at least 1400 bases would be even better.

Also on page 7 of his Answer, the Examiner contends that Appellants do not describe how the GLP-2R promoter construct will react to the presence of "inducers or

suppressors of expression.” Appellants submit that this is irrelevant, because the GLP-2R promoter construct is designed to function in the same tissues in which the GLP-2R gene naturally functions. Thus, the skilled person, informed by the present specification, simply need know the tissues in which the GLP-2R gene naturally functions. By the same token, disclosure related to the intricacies of the GLP-2R promoter’s interaction with specific inducers or suppressors has no bearing on the descriptive sufficiency of the application vis-à-vis the appealed claims.

Finally, the Examiner erroneously argues that the scope of claim 1 is indefinite. The subject matter of the claim 1 covers “a promoter region comprising at least 1000 bases upstream of the transcription start site.” Therefore, the claim covers a promoter region at least 1000 bases long, a promoter region over 8000 bases upstream of the transcription start site, as well as a promoter region of bases of any nucleotide length in between and including these specific lengths. In other words, the phrase “promoter region” encompasses a partial sequence (at least 1,000 bases) as well as the entire nucleotide sequence of the GLP-2R promoter region.

The following mistakes of fact, also reflected in the Examiner’s Reply, are addressed only briefly, since they were considered the Appeal Brief. First, the Examiner mistakenly alleges that the specification and claims do not identify the necessary structural and functional similarities between the endogenous GLP-2R gene promoter and the GLP-2R promoter sequence. As the Appeal Brief points out, the sequence encompassing “at least the last 1000 nucleotides upstream of the transcription start site” correlates with the function of the endogenous GLP-2R promoter region. Specification, paragraph 43. Further, the specification at paragraph 123 identifies a high functional similarity between the mouse GLP-2R promoter region construct and the endogenous mouse GLP-2R promoter in the specification. Accordingly, the Examiner is mistaken that these structural and functional similarities were not identified in the claims and the specification.

Additionally, with respect to claims 1-5 and 9-11, the Examiner maintains that the specification does not sufficiently define the phrase “promoter region of the GLP-2R gene.” As set forth in Appellants’ Appeal Brief, the specification in paragraph 43, defines the promoter region as the region on the GLP-2R gene “which drives expression of the endogenous GLP-2R gene ... [and] begins 5’ to the first base of the 5’-UTR and

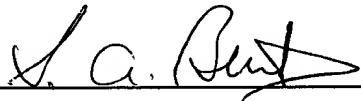
extends upstream therefrom to include, minimally, the number of bases necessary to drive transcription... ." The specification thus defines the "promoter region of the GLP-2R gene" by its nucleotide length, location on the GLP-2R gene, and its function. Specification, paragraphs 43 and 44. Further, the function of the GLP-2R promoter region construct is shown to be highly similar to the function of the endogenous GLP-2R promoter region. Specification, paragraph 123.

Conclusion

Appellants submit that the specification does provide sufficient description to evidence their possession of the claimed invention. Furthermore, Appellants submit that the claims are definite, within the meaning of Section 112. They renew their request, therefore, for a reversal of the appealed rejections.

Respectfully submitted,

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